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REMARKS

The present response is intended to be fully responsive to all points of objection and rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Status of Claims

Claims 1-11 and 13-20 are currently pending in the application. Claims 1-11 and 13-20 have been rejected. Claims 1-2 and 4-20 have been amended.

Claim 3 has been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in this claim to file divisional and/or continuation patent applications.

New claims 21-31 have been added in order to further define what the Applicants consider to be the invention. Applicants respectfully assert that no new matter has been added.

Claims 4-10 and 13-20 have been voluntarily amended for clarification only. These amendments do not narrow the scope of the claims, nor are they being made for reasons of patentability.

Applicants respectfully assert that the amendments to the claims and drawings add no new matter.

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Remarks to the Specification

The amendments to the specification are editorial in nature and do not introduce new matter.

Remarks to the Drawings

Original sketched Figs. 1-5 have been replaced by drafted Figs. 1-5. The drawing sheets containing the corrected drawings are attached for review by the Examiner.

Drawings Rejections

The drawings have been objected to for not showing every feature of the invention specified in the claims. The replacement drawings show every feature of the invention specified in the claims, therefore this rejection is now moot.

Claim Objections

In the Office Action, the Examiner objected to claims 1-11 and 13-20 because of alleged informalities. Amended claims 1-2, 4-11 and 13-20 cure these informalities. Accordingly, Applicants request withdrawal of these objections.

CLAIM REJECTIONS

35 U.S.C. § 101 Rejections

In the Office Action, the Examiner rejected claims 1-11 and 13-20 under 35 U.S.C. § 101, because the claimed invention is alleged to be directed to non-statutory subject matter.

Claims 1, 2, 4, 5, 6, 7, 8, and 11 have been amended, in accordance to the Examiner's suggestion to use language similar to "adapted to be", to overcome the antecedent basis deficiencies noted by the Examiner. It is respectfully asserted that the foregoing amendments merely address matters of form and do not change the literal scope of the claims in any way.

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Applicants respectfully request that the rejections to claims 1-11 and 13-20 under 35 USC 101 be withdrawn.

35 U.S.C. § 102 Rejections

In the Office Action, the Examiner rejected claims 1-2, 9-11 and 13-14 under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent Number 5,429,144 to Wilk.

The Examiner asserted that Wilk discloses a chronic implant apparatus comprising a shunt (12), implanted in a puncture of a septum (Hardware), wherein the shunt is a tubular element having two ends, each end comprising a tissue fixation element.

In response, Applicants respectfully traverse this rejection in view of the remarks that follow. The Examiner alleges that Wilk expressly describes an apparatus and method that include extending a stent from the left ventricle to an artery, for example, "disposing the stent in a wall of the patient's heart so that the stent extends between the left ventricle of the heart and the coronary artery and extends only within the wall and not into the left ventricle or the coronary artery." (see column 1, lines 56-61). Wilk does not disclose extending a stent between chambers of the heart. Further, Wilk discloses a one-way valve. For example, "During diastole, the blood pumped into coronary artery through shunt 66 is blocked by oneway valve 68 from returning to left ventricle LV" (see column 6, lines 24-26). Wilk does not disclose or suggest selectively permitting blood flow between the heart chambers, and does not disclose or suggest using selected pressure thresholds for controlling blood flow. Wilk, therefore, does not disclose or suggest "selectively permitting blood flow between the first chamber and a second chamber of a heart at a selected pressure threshold" as described in amended independent claim 1, or "whereby a volume of blood sufficient to reduce pressure in the first chamber, when said pressure reaches a selected threshold, is released from the first chamber to said second chamber", as described in amended independent claim 11.

Applicants hereby amend independent claim 1 to include "a valve element, said valve element adapted to enable selectively permitting blood flow between the first chamber and a second chamber of a heart at a selected pressure threshold". Support for the valve element may be seen, for example, in paragraph 22 of the specification of the present invention:

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valve element 130 may be either passive (actuated by the force of blood) or active (actuated by some other portion of the device). In active valve embodiments, the valve element 130 may include electric or electromagnetic elements that can be selectively actuated to open and close the valve element 130 or, if the valve element is designed for gradual opening and closing, move the valve element 130 between a first positions and a second position. These embodiments will provide robust and reliable functionality by being mechanical and operating with signal inputs.

Further, Applicants hereby amend independent claim 11 to include "the method comprising implanting a shunt adapted to communicate with a second chamber outside the first chamber, whereby a volume of blood sufficient to reduce pressure in the first chamber, when said pressure reaches a selected threshold, is released from the first chamber to said second chamber".

Accordingly, Applicants respectfully assert that amended independent claims 1 and 11 are allowable. Claims 2, 4-10 and 12-31 depend from, directly or indirectly, claims 1 and 11, and therefore include all the limitations of those claims. Therefore, Applicants respectfully assert that claims 2, 4-10 and 12-31 are likewise allowable. Accordingly, Applicants respectfully request that the Examiner withdraw the rejections to amended independent claims 1 and 11 and to claims 2, 4-10 and 12-31 dependent thereon.

35 U.S.C. § 103 Rejections

In the Office Action, the Examiner rejected claims 3-4 under 35 U.S.C. § 103(a), as being unpatentable over Wilk. Applicants respectfully traverse the rejection of claims 3-4 under Wilk.

As discussed above, independent claim 1 is now in condition for allowance. Claims 3-4 depend, directly or indirectly, on claim 1, and are therefore in condition for allowance.

In the Office Action, the Examiner rejected claims 5, 7-8, 15 and 17-20 under 35 U.S.C. § 103(a), as being unpatentable over Wilk in view of U.S. Patent Number 6,210,318 to Lederman. Applicants respectfully traverse the rejection of claims 5, 7-8, 15 and 17-20

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under Wilk in view of Lederman, as it would not have been obvious to one skilled in the art at the time of the conceptualization of the present invention to use the stent of Wilk together with the pump system of Lederman to provide the apparatus and method of the present invention.

As discussed above, independent claims 1 and 11 are now in condition for allowance. Claims 5, 7-8, 15 and 17-20 depend, directly or indirectly, on claims 1 and 11 respectively, and are therefore in condition for allowance.

In the Office Action, the Examiner rejected claims 6 and 16 under 35 U.S.C. § 103(a), as being unpatentable over Wilk in view of U.S. Patent Number 6,632,169 to Korakianitis. Applicants respectfully traverse the rejection of claims 6 and 16 under Wilk in view of Korakianitis, as it would not have been obvious to one skilled in the art at the time of the conceptualization of the present invention to use the stent of Wilk together with the pump device of Korakianitis to provide the apparatus and method of the present invention.

As discussed above, independent claims 1 and 11 are now in condition for allowance. Claims 6 and 16 depend, directly or indirectly, on claims 1 and 11 respectively, and are therefore in condition for allowance.

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

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Please charge any fees associated with this paper to deposit account No. 05-0649.

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pectfully submitted,

Dated: September 28, 2004

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